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Requirements for Product Technology Transfer ...

Technology Transfer: a Collaborative Approach to Improve ...

WHO GUIDELINE ON TRANSFER OF TECHNOLOGY DRAFT DOCUMENT FOR COMMENT The need for new WHO guidance for transfer of technology was discussed at the forty-second meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2007. Colleagues from the WHO Prequalification Programme pharmaceutical quality system should in-

corporate appropriate risk management principles. While some aspects of the pharmaceutical quality system can be company-wide and others site-specific, the effectiveness of the pharmaceutical quality system is normally demonstrated at the site level.

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Guidance for Industry Q10 Pharmaceutical Quality System

Annex 7 WHO guidelines on transfer of technology in ...

A Technology Transfer Plan: The objective is to transfer expertise, technical information (e.g. concerning raw materials and specifications), and technologies. A technology transfer plan (which often takes the form of a GANTT chart, as in Figure 5) should include the sequence of all transfer activities.

IMAGE COURTESY OF THE AUTHOR Technology scale-up and transfer are common—and crucial—biodevelopment activi-

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pharmaceutical quality system to enhance the quality and availability of medicines around the ... • Technology Transfer o New product transfers during development through manufacturing

A technology transfer is what happens when a pharmaceutical company wants to change from an existing manufacturing site to a new manufacturing site

The adoption of Resolution WHA61.21 for the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) brought a renewed focus on local production and related technology transfer as a strategy to promote innovation, build capacity and improve access to quality-assured medical products.

Technology Transfer and Pharmaceutical Quality Systems

Technology Transfer | Pharmaceutical Technology

Pharmaceutical Technology spoke with Roger Croucher, senior manager, R&D projects, at Catalent Pharma Solutions; Daniel M. Bowles, senior director, chemical development, at Cambrex; and Kurt J Kiewel, director, new product development and analytical services, also at Cambrex about best practices for a successful technology transfer.

WHO | Local production & technology transfer for access to ...

The main objective of this study is to provide the clear procedure for technology transfer process in pharmaceutical industry. Technology transfer is a process to transfer information and technologies necessary to manufacture quality drug product consistently or technology transfer is the process of taking an invention from its inception in a laboratory to a commercialized product.

Review on Technology Transfer in Pharmaceutical Industry

technology transfer depends upon process understanding or the ability to predict accurately the future performance of a process. Keywords: Technology transfer, pharmaceutical production, Research and development INTRODUCTION A proper tech-

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ICH guideline Q10 on pharmaceutical quality system - Step 5

WHO guidelines on transfer of technology in pharmaceutical manufacturing 1. Introduction 2. Scope 3. Glossary 4. Organization and management 5. Production: transfer (processing, packaging and cleaning) 6. Quality control: analytical method transfer 7. Premises and equipment 8. Documentation 9. Qualification and validation References

Technology Transfer Guidelines for Pharmaceuticals ...

Technology Transfer And Pharmaceutical Quality

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Scale-up & Technology Transfer as a Part of Pharmaceutical Quality Systems George P. Millili, Ph.D. Senior Director Pharmaceutical Commercialization

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